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November 10, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 92N-0297 Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administration Procedures; Public Hearing

Dear Sir or Madam:

Novartis Pharmaceuticals Corporation ("Novartis") is pleased to provide comments on the PDMA final rule provisions and questions raised in the above-referenced notice. Novartis believes that the provisions of the Prescription Drug Marketing Act of 1987 and related Amendments ("PDMA") pertaining to the wholesale distribution of prescription drugs were intended to prevent distribution of counterfeit drugs in the United States. Novartis supports the use of drug "pedigrees" that establish a "chain of custody" of products and establishes their authenticity. This is an even greater concern when prescription drugs may be re-imported for sale into the United States from foreign distributors.

The notice included several specific questions regarding the planned implementation of the final PDMA rule. We would like to take this opportunity to address several of the issues raised by FDA that are pertinent to the pharmaceutical industry.

Potential impact of PDMA final rule on unauthorized wholesalers

Novartis does not dispute the fact that the requirement for "unauthorized distributors", that is, those who have not established an ongoing relationship to distribute a manufacturer's products, to obtain a drug pedigree may be difficult for many smaller wholesalers. However, we believe that such a requirement is in the public interest, by documenting a "chain of custody" for prescription drugs that are being distributed. Such a procedure would help document that products are handled and stored appropriately, and facilitate tracking and recall efforts, should they become necessary. This is especially important for products that may be sold by US wholesalers to foreign distributors and then later re-imported for sale in the US. Novartis encourages FDA to consider the impact of PDMA regulations when developing regulations for the recently approved re-importation law.

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Potential impact of PDMA final rule on the public health and drug distribution system

Implementation of the final rule would have no negative impact on public health. Indeed, the impact is positive because the requirement of a drug pedigree to establish its authenticity and purchase and distribution history is in the public interest. The existence of such a document can serve as a reasonable assurance to dispensing pharmacists that the products delivered to their shelves by wholesale distributors are not counterfeit, and have been stored and handled appropriately.

The drug distribution system should not be significantly impacted, since most distributors are already following the procedures described in the final rule as a matter of sound pharmaceutical practice.

Potential impact of deleting the drug pedigree requirement

The drug pedigree requirement cannot, in and of itself, serve as the sole protection against the distribution of counterfeit, adulterated, misbranded or otherwise unsuitable drugs to consumers and patients. However, the deletion of this requirement from PDMA would remove an existing barrier to the introduction of these types of unsuitable products to patients. This will become even more important if a drug is re-imported for sale in the US after traversing distribution systems that are not bound by the requirements of PDMA. The lack of a pedigree requirement will make it easier for potentially counterfeit , misbranded or unsuitable products introduced into these distribution systems to find their way onto the shelves of US pharmacies.

Potential impact of requiring authorized distributors to provide a pedigree

Such a requirement could lead to a dramatic increase in the number of unauthorized distributors many of which, despite their ability to obtain a state license, may not be sufficiently equipped to provide the necessary storage and delivery of large inventories of pharmaceutical products. This would lead to the sudden appearance of numerous very small, "niche" distributors which would not need to establish any relationships with manufacturers, but would merely obtain the required pedigree from an authorized distributor in order to conduct wholesale transactions of their own. These new niche distributors would be extremely difficult to regulate and would have never demonstrated their ability to ensure the integrity of pharmaceutical products. In addition, the administrative burden on authorized distributors to provide pedigrees to "all comers" would be extremely onerous, and likely result in higher prices for consumers.

Potential impact of changing the criteria to define an authorized distributor

The current criterion, the requirement that a "manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products" is sufficient and appropriate. In fact, the use of actual sales to a distributor as the sole determinant of an "ongoing relationship" with a manufacturer would likely serve little purpose, since manufacturers typically do not sell products to distributors without some form of written agreement or contract. A change would, however, enable any distributor producing "proof" of such a purchase to claim they are an "authorized distributor", and therefore not required to provide a drug pedigree.

Novartis believes that the intent of the PDMA was to ensure the integrity of the pharmaceutical supply chain and eliminate counterfeit drugs in the United States by establishing a chain of custody for drugs. Enforcement of the pedigree system will be an especially important public

health protection as FDA develops regulations to implement recently passed re-importation legislation.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Timothy J. Sayles, PharmD
Associate Director, Healthcare Policy

cc: R. Bantham, PhRMA